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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,885	03/22/2004	John W. Benbow	PC25078A	2214

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PFIZER INC.  
PATENT DEPARTMENT, MS8260-1611  
EASTERN POINT ROAD  
GROTON, CT 06340

EXAMINER

TUCKER, ZACHARY C

ART UNIT PAPER NUMBER

1624

DATE MAILED: 08/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/805,885

Applicant(s)

BENBOW ET AL.

Examiner

Zachary C. Tucker

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

***Response to Amendment***

As requested in the 13 July 2006 correspondence from applicants' counsel (hereinafter "present amendment"), which is in reply to the Office action mailed 24 April 2006 (hereinafter "previous Office action"), claims 1-5 have been amended and claims 6-14 have been cancelled.

***Requirement for Restriction***

Withdrawn claims 6-14 are cancelled by virtue of the present amendment. Claim 5 remains withdrawn because the claims of elected Group I are not in condition for allowance. Upon allowance of the claims of the elected Group, claim 5 will be rejoined.

***Status of Claim Rejections - 35 USC § 112***

In the previous Office action, claims 1-4 were rejected under the first and second paragraphs of 35 U.S.C. 112, for lack of a disclosure enabling one of ordinary skill in the art to produce the claimed prodrugs of formula (I) compounds and salts thereof, and because the claimed "prodrugs" were of indeterminate chemical structure.

Claim 4 was found to be indefinite, in addition to depending from indefinite claim 1, because the fourth named species in that claim does not find antecedent basis in claim 1.

By virtue of the present amendment, the rejections have been overcome, because "prodrug" has been struck from the claims and the fourth named species has been struck from claim 4. Rejections of claims 1-4 under 35 U.S.C. 112 are hereby withdrawn.

**Status of Claim Rejections - 35 USC § 103**

In the previous Office action, claims 1-4 were rejected under 35 U.S.C. 103(a) as being unpatentable over Sarges et al, *Journal of Medicinal Chemistry*, vol. 33(8), pages 2240-2254 (1990).

The proviso recited in claim 1, which eliminates from the scope of that claim those compounds described by the case where R<sup>a</sup> is hydrogen and R<sup>b</sup> is hydrogen or isopropyl and R<sup>1</sup> is fluoro, has been amended to now exclude all compounds wherein R<sup>a</sup> is hydrogen and R<sup>b</sup> is hydrogen or isopropyl and R<sup>1</sup> is any halogen. As such, the claim no longer embraces compounds taught by Sarges et al, because the only compounds disclosed in the reference wherein the variable "X" is OH – which tautomerizes to the carbonyl in formula (I) of the instant claims – are those wherein fluorine is at the 8-position, which corresponds to R<sup>1</sup> of formula (I) of the instant claims. A general teaching is found in Sarges et al which suggests replacement of an 8-fluoro substituent with an 8-chlorine substituent, but not any other substituent at the 8-position. So, the reference no longer suggests compounds according to instant claims 1-4, therefore the rejection based on Sarges et al is hereby withdrawn.

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**New Claim Rejection - 35 USC § 112**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

Art Unit: 1624

in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the amendment to claim 1, in which the proviso excluding the from formula (I) those compounds wherein  $R^a$  is hydrogen and  $R^b$  is hydrogen or isopropyl and  $R^1$  is fluoro has been changed so that "fluoro" is now "halogen," in other words, the compounds wherein  $R^a$  is hydrogen and  $R^b$  is hydrogen or isopropyl and  $R^1$  is chloro, fluoro, bromo and iodo are now excluded from claim 1.

Applicants' counsel has not indicated where in the disclosure the support for this amendment is found. In fact, the only proviso mentioned in the disclosure is the proviso which was present in claim 1 as originally presented, wherein the fluoro substituted compounds are excluded. Applicants at page 6 define "Halogen", line 7 to be chloro, fluoro, bromo and iodo. MPEP 2173.05(i) directs the examiner to reject exclusionary provisos not having support in the disclosure as new matter.

To summarize, as originally presented, the claims and specification described compounds according to formula (I), and excluded from the scope of that formula those compounds wherein the variable  $R^a$  is hydrogen and the variable  $R^b$  is hydrogen or isopropyl and at the same time  $R^1$  is fluoro. Now, that same proviso has been amended so that "fluoro" is replaced with "halogen." The specification does not describe compounds of formula (I), excluding from the scope thereof those compounds wherein the variable  $R^a$  is hydrogen and the variable  $R^b$  is hydrogen or isopropyl and at the same time  $R^1$  is *halogen*.

***Allowable Subject Matter***

Should the new rejection under 35 U.S.C. 112, first paragraph be overcome, preferably by revisiting the language of the proviso in claim 1 as was originally presented, and amending the other variables so that the compounds suggested by Sarges et al, as applied in the previous Office action, are not embraced by formula (I), claims 1-4 will be allowed, claim 5 will be rejoined and allowed.

Deleting hydrogen and replacing (C<sub>1</sub>-C<sub>6</sub>)alkyl with (C<sub>5</sub>-C<sub>6</sub>)alkyl in the definition of R<sup>a</sup> and R<sup>b</sup> would render the compounds of formula (I) unobvious over Sarges et al.

***Conclusion***

Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached

Art Unit: 1624

Monday to Friday from 5:45am to 2:15pm. If Attempts to reach the examiner are unsuccessful, contact the examiner's supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

zt

A handwritten signature in black ink, appearing to be "Zach" followed by a long horizontal line.